NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS ADVISORY COUNCIL

September 11, 2015

National Institutes of Health Bethesda, MD

MINUTES

The National Deafness and Other Communication Disorders Advisory Council convened on September 11, 2015 in Building 31, Conference Room 6, National Institutes of Health (NIH), Bethesda, MD. Dr. James F. Battey, Jr., Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Chairperson. In accordance with Public Law 92-463, the meeting was:

Closed: September 11, 2015: 8:30 a.m. to 10:05 a.m. for review of individual grant applications; and

Open: September 11, 2015: 10:05 a.m. to 1:45 p.m., for the review and discussion of program development needs and policy.

Council members in Attendance¹:

Dr. Sarah Blackstone
Dr. Diane Bless
Dr. Tommie Robinson
Ms. Joan Kaye
Dr. Robert Shannon
Dr. Sue Kinnamon
Dr. Helen Tager-Flusberg
Dr. Jian-Dong Li
Dr. Charles Liberman
Dr. David Myers
Dr. Tommie Robinson
Dr. Robert Shannon
Dr. Helen Tager-Flusberg
Dr. Monte Westerfield
Dr. Donald Wilson

Council members absent:

Dr. Joseph Perkell Dr. Richard Smith Dr. Elba Serrano Dr. Debara Tucci

Ex-Officio Members Participating:

Dr. Rick Davis

The complete Council roster is found in Appendix 1.

¹For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a real or apparent conflict of interest might occur. This procedure applies only to individual discussion of an application and not to "en bloc" actions.

NIDCD employees present during portions of the meeting:

Dr. Kathy Bainbridge Dr. Castilla McNamara Dr. James Battey Dr. Roger Miller Mr. Jim Burton Mr. Christopher Myers Dr. Laura Cole Mr. Edward Myrbeck Mr. Eric Nunn Dr. Judith Cooper Dr. Janet Cyr Dr. Christopher Platt Ms. Susan Dambrauskas Dr. Kausik Ray Mr. Hoai Doan Mr. Mark Rotariu Dr. Amy Donahue Dr. Lana Shekim Dr. Nancy Freeman Dr. Sheo Singh Ms. Maria Garcia Dr. Elka Scordalakes Dr. Andrew Griffith Ms. Nanette Stephenson Dr. Steven Hirschfeld Dr. Melissa Stick Mr. Howard Hoffman Dr. Susan Sullivan Ms. Debbie Holmes Dr. Jean Tiong-Koehler Ms. Nichelle Johnson Dr. Bracie Watson Dr. Craig Jordan Ms. Ginger Webb Ms. Phalla Keng Mr. Timothy Wheeles Dr. Lisa Kennedy Mr. Baldwin Wong

Other federal employees present during portions of the meeting:

Dr. Eliane Lazar-Wesley

Dr. Chuan-Ming Li

Dr. Laurence Tabak, Office of the Director, NIH

Dr. Nick Gaiano, Center for Scientific Review, NIH

Dr. Biao Tian, Center for Scientific Review, NIH

Ms. Christi Themann, Centers for Disease Control and Prevention, HHS

Dr. Shiguang Yang

Dr. Andrea Kellev. Center for Scientific Review. NIH

Dr. Wind Cowles, Center for Scientific Review, NIH

Members of the public present during open portions of the meeting:

Dr. Richard Hillman, Massachusetts Eve and Ear Infirmary

Ms. Susan Lott, American Speech-Language-Hearing Association

Ms. Tanya Holmes, National Association of the Deaf

Mr. Steve Saenz, Access Interpreting, Inc.

Ms. Krystin Balzarini, Access Interpreting, Inc.

CLOSED SESSION

I. Call to Order and Opening RemarksDr. James F. Battey, Jr.

The meeting was called to order by Dr. Battey, Director, NIDCD, who expressed appreciation to the entire Council for their service and advice. Drs. Blackstone, Kinnamon, Liberman and Wilson were welcomed to the group as new council members with the promise of a more formal introduction in the Open Session.

II. Council Procedures......Dr. Craig A. Jordan

Procedural Matters

Dr. Jordan discussed important procedural matters, including requirements imposed by the Government in the Sunshine Act and the Federal Advisory Committee Act. The necessity of members to avoid conflict of appearance thereof was stressed, as was the need to maintain confidentiality concerning the proceedings and materials related to the closed portion of the meeting. Dr. Jordan announced that the Council meeting would be closed for consideration of grant applications during the morning session, but would be open to the public at approximately 10:00 a.m.

III. Council Consideration of Pending Applications

A. Research Project Grant Awards

Consideration of Applications: On the Council's agenda was a total of 123 investigator-initiated research grant applications; 106 applications had primary assignment to NIDCD, in the amount of \$35 million first-year direct costs. It is anticipated that, of the applications competing at this Council, NIDCD will be able to award grants to R01 applications scoring up through the 14th percentile.

B. Special Programs Actions

- 1. NIH Research Career Enhancement Award for Established Investigators (K18): The Council recommended support of one application.
- 2. NIH Pathway to Independence (PI) Award (K99): The Council recommended support of two applications.
- 3. NIH Small Grants (R03): The Council recommended support of nine applications.
- 4. NIH Support for Conferences and Scientific Meetings (R13): The Council recommended support of four applications.
- 5. NIH Academic Research Enhancement Awards (AREA) (R15): The Council recommended support of one application.
- 6. NIH Exploratory/Development Research Grant Award (R21): The Council recommended support of seven applications.
- 7. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support of two Phase I (R43) applications.

- 8. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support of three Phase II (R44) applications.
- 9. NIDCD Research on Hearing Health Care (R21/R33): The Council recommended support of three applications.

Next, Dr. Battey welcomed Dr. Andrew Griffith, Director of NIDCD's Division of Intramural Research. As stipulated by law, each institute must provide annually to its National Advisory Council an overview of the Intramural Research Program. The overview includes reports of the Board of Scientific Counselors (BSC), and the responses of the Scientific Director. This presentation is informational; Council members are not asked to recommend approval or disapproval of the reports or to modify them in any way. However, the Council may make recommendations to the Director, NIDCD regarding such research on the basis of the materials provided.

Dr. Griffith presented Reports of the BSC regarding the review of several intramural laboratories. He then presented his responses to the reports and responded to questions from Council.

[Executive Secretary Note: During the BSC presentation, attendance was restricted to the Council members, the Executive Secretary and a few senior NIDCD administrators.]

OPEN SESSION

Dr. Battey welcomed additional staff and visitors to the open session of the meeting.

Recognition of New Members

- Dr. Battey welcomed the following new members to the Advisory Council:
 - <u>Dr. Sarah Blackstone</u> is President and CEO of Augmentative Communications Inc. and Partner Emeritus at Rehabilitation Engineering Research Center on Communication Enhancement and coordinates the Patient-Provider Communication group. She received her doctoral degree in Speech-Language Pathology from the University of Pittsburgh and has a clinical certification in Speech-Language Pathology. Her professional interests include examining the communication process. She is well known for her work on Augmentative and Alternative Communication (AAC) and patient-provider communication. She has authored multiple texts in the field of augmentative and alternative communication, as well as Augmentative Communication News. The newsletter provides an informed synopsis of what AAC experts around the world are doing and thinking. Dr. Blackstone worked at Johns Hopkins Medical Center in Baltimore and in a private practice that served children and adults with complex communication needs. She has received numerous awards and served in many leadership roles, for example the Board of Directors for The Bridge School.
 - <u>Dr. Sue Kinnamon</u> is a Professor at the University of Colorado-Denver. Dr. Kinnamon received her doctoral degree in Neuroscience from Kansas State University. She has a joint appointment with the Department of Cell and Developmental Biology and the Department of Physiology and Biophysics at the University of Colorado-Denver. Her research interests focus on the mechanisms used by the taste receptor cells to detect sweet, salty, sour, bitter, and umami in the foods we eat; many of her projects received NIH funding. Dr. Kinnamon has had editorial/reviewer responsibilities for several journals, has served as a peer reviewer for NIH

and NSF. She is a member of various professional organizations such as the Society for Neuroscience and Association for Chemoreception Sciences (AChemS). She has held many prominent roles on committees of the AChemS over the past 20 years. Dr. Kinnamon has published extensively, and received many honors and awards, such as the AChemS Award for Outstanding Achievement.

- <u>Dr. Charles Liberman</u> is the Harold F. Schuknecht Professor of Otology and Laryngology and the Vice Chair of Research in the Department of Otolaryngology at Harvard Medical School. In addition he is the Director, Eaton Peabody Laboratory at Massachusetts Eye and Ear Infirmary. Dr. Liberman received his doctoral degree in Physiology from Harvard University. His research interests include neuroanatomy and neurophysiology of the peripheral auditory system, efferent feedback pathways to the auditory periphery, stimulus coding in the auditory nerve in normal and pathological ears, acoustic trauma and other ototraumatic agents. Dr. Liberman's work has shown that efferent feedback helps us discriminate sounds in a noisy environment and protects the inner ear from damage following overexposure to loud sounds. Dr. Liberman is widely published and has received numerous honors and awards, including the Bekesy Medal from the Acoustical Society of America. He has served on the NIDCD Communication Disorders Review Committee and Board of Scientific Counselors as both a member and Chair.
- Dr. Donald Wilson is a Senior Research Scientist and Deputy Director at the Emotional Brain Institute at the Nathan S. Kline Institute for Psychiatric Research and Professor at the New York University Langone School of Medicine. He received is doctoral degree in Physiological Psychology from McMaster University. His research interests involve understanding how the mammalian brain processes and remembers information. Dr. Wilson focuses on perceptual learning, sensory gating, object coding, and hedonic coding in the mammalian olfactory system. He is particularly interested in how experience can shape sensory coding resulting in change in perceptual activity as well as associating emotional meaning to sensory objects. He is a member of the Society of Neuroscience and Association for Chemoreception Sciences and received the Max Mozell Award for Outstanding Achievement in the Chemical Senses. Dr. Wilson is widely published, and has received significant research funding from NIH, NSF, and other organizations. He has served on many editorial boards and provided significant professional service as a peer reviewer.

Consideration of Minutes of the Meeting of May 29, 2015

Dr. Battey called the members' attention to the minutes of the May 29, 2015 meeting of the Advisory Council. The minutes were approved as written.

Confirmation of Dates for Future Council Meetings

Dates for the Council meetings through September 2017 have been established. A list of these meetings was distributed to the Council members and posted on the web site prior to this meeting. The next meeting of the Council is scheduled for Friday, January 22, 2016, in Building 31, Conference Room 6 on the NIH campus, Bethesda, Maryland.

NIH policy requires that the National Advisory Council for each institute review the activities of their respective intramural program once a year. Dr. Andrew Griffith, Scientific Director of NIDCD's Division of Intramural Research presented the 2015 report.

Board of Scientific Counselors

Dr. Griffith updated the Council on the membership of the Board of Scientific Counselors. Dr. Andrew Groves from the Baylor College of Medicine is the Chair of the committee; the committee currently has 8 members and on average 20% of the membership is replaced annually.

Personnel

There are currently 11 tenured investigators and two tenure-track investigators along with a large contingent of supporting scientists. During the past year, Dr. Lisa Cunningham moved from Tenure-Track to a Tenured position. In response to last year's recruitment efforts, Dr. Catherine Weisz will join NIDCD next moth as a Tenure-Track scientist. Dr. Weisz earned her Ph.D. in Neuroscience from Johns Hopkins University and will come to the NIH from the University of Pittsburgh where she was working with Karl Kandler. There are currently four individuals in the Surgeon-Scientist Career Development program.

Highlights

Dr. Griffith provided information about the NIDCD's Otolaryngology Surgeon-Scientist Program that is geared toward an integration of clinical and basic research opportunities in a mentored environment. The goal is to provide early career faculty development through graduated independence and resources. In addition, the intramural program provides a culture of scholarly inquiry and scientific rigor in conjunction with opportunities to maintain their important surgical skills.

The second *EARssentials course* was held in June, 2015 at the Porter Neuroscience Research Center with the main focus being, "Concepts and Techniques of Contemporary Hearing Research". The primary target audience was new NIDCD intramural trainees, however, the course was offered free of charge and was open to any interested individual, even scientists from outside the NIH. The week long course included morning lectures and afternoon laboratory sessions

VII. Report of the Director, NIDCDDr. Battey

Budget Update

Dr. Battey began his presentation by displaying a limited budget slide which included the current fiscal year (FY) 2015 operating level of \$405.2 M, the President's NIDCD Budget Request (\$416.2M) for fiscal year FY 2016 and proposed numbers from the House and Senate Appropriation Committees. He pointed out that unlike the past few years both Congressional Committees have endorsed increases for NIDCD, however, these bills have not been brought to the floor of either chamber for a vote. As a consequence, there is a great deal of uncertainty about what the eventual budget level will be and it is very likely that NIH will begin FY 2016 without an appropriation, operating under a Continuing Resolution. Because the first appropriations measure that the Congress will pass is likely to be a Continuing Resolution at, or a fraction of, the FY 2015 level, NIDCD has taken what we believe is a conservative approach to modeling the FY 2016 budget and the R01 automatic payline. We remain hopeful that whatever annual appropriations measure eventually enacted contains a modest increase.

[A copy of the slides Dr. Battey used for this budget presentation is included in Appendix 2.]

VIII. Ambulatory Monitoring and Biofeedback for Assessing and Dr. Robert Hillman Treating Voice Disorders

Many common voice disorders are chronic or recurring conditions that are likely to result from faulty and/or abusive patterns of vocal behavior referred to generically as *vocal hyperfunction*.

Such behaviorally based disorders can be difficult to accurately assess in the clinical setting and could potentially be much better characterized by long-term ambulatory monitoring of vocal function as individuals engage in their typical daily activities. This presentation will provide an update about ongoing NIDCD-funded research that is aimed at developing ambulatory monitoring of vocal function into a valid, reliable, and cost-effective clinical tool that can be used to accurately identify and differentiate patterns of voice use that are associated with hyperfunctional voice disorders. The current system (called the Voice Health Monitor – VHM) uses an unobtrusive miniature accelerometer placed on the neck skin above the collarbone as the phonation sensor and a smartphone as the data acquisition platform. A major focus of this work is the application of vocal system modeling and machine learning approaches to extract new more sensitive/salient measures of vocal function from the large amounts of data produced by ambulatory monitoring. Efforts to further develop the VHM system to provide ambulatory biofeedback for behavioral treatment of hyperfunctional voice disorders will also be described. (Funded by NIH-NIDCD 5R33DC011588-05).

Dr. Cooper began by introducing Dr. Steven Hirschfeld who has been providing NIDCD with direction, oversite and superb management of our clinical trials program since last February, following the untimely death of Dr. Gordon Hughes. Steven's official position is the Associate Director for Clinical Research at the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), where he oversees clinical research centers, clinical trials and policy. NICHD has graciously allowed Steven to provide his expertise on an as-needed basis.

Dr. Hirschfeld, who is a pediatrician specializing in hematology and oncology, trained at Columbia University and UCSF, and previously worked at the National Cancer Institute (NCI) and the Food and Drug Administration. To mention only a few of his contributions, Steven was one of the scientific co-chairs of the 2011 Global Research in Pediatrics, a European Commission initiative to facilitate the development of medicinals for children and has also served as a consultant for such organizations as the World Health Organization, and the Institute of Medicine. From mid-2009 through 2014 he was initially the Acting Director, then the Director of the National Children's Study. As a member of the Public Health Service, Dr. Hirschfeld has deployed regularly on humanitarian and disaster relief missions around the country, including deployments to Louisiana and Texas because of hurricanes and most recently in 2012 to New York City for Superstorm Sandy.

NIDCD is pleased to have Steven as a member of our team. All are encouraged to consult him with any issues related to clinical trials.

Dr. Cooper introduced Dr. Janet Cyr, NIDCD Program Officer, who provided a summary of a recent NIDCD workshop entitled "Synaptopathy and Noise-Induced Hearing Loss: Animal Studies and Implications for Human Hearing" held on May 4-5, 2015. The focus of this NIDCD workshop was to identify barriers to, and opportunities in, the area of noise-induced synaptopathy and to articulate unmet research needs as the scientific community looks to translate these animal studies into the realm of the human auditory system and the clinic. The workshop was organized by Dr. Cyr and Dr. Amy Donahue, in the NIDCD Division of Scientific Programs. Dr. Sharon Kujawa and Dr. M. Charles Liberman co-chaired the workshop and sixteen auditory scientists from the U.S. and abroad were invited to bring their expertise to the discussion. The workshop was open to all interested members of the scientific community and public.

The workshop was focused on the loss of hair cell-auditory nerve synapses as the result of noise exposure. Recent animal studies have revealed substantial irreversible neural degeneration following temporary noise-induced elevation of auditory threshold, i.e., temporary threshold shift (TTS). Despite no hair cell loss and recovery of threshold sensitivity, exposed animals demonstrated extensive loss of a subset of synaptic connections between cochlear hair cells and auditory nerve terminals and a delayed degeneration of spiral ganglion cells and their central

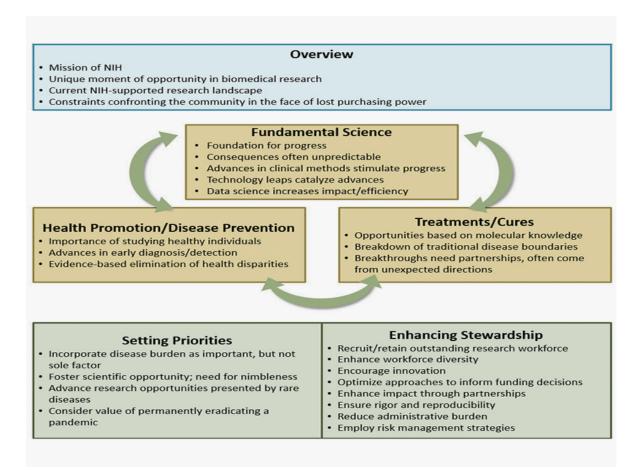
projections. Based upon the subset of connections that are lost, it is proposed that this type of synaptic loss may underlie a common patient complaint of having difficulty detecting speech in noise.

Over a period of several months, workshop participants engaged in a series of pre-meeting conference calls to begin to identify the challenges and opportunities in four specific areas of current auditory synaptopathy research: animal studies, human electrophysiology, human psychophysical studies, and mechanisms and potential treatments. The participants then convened in Bethesda, MD on May 4th and 5th. The workshop began on May 4th with a few introductory talks followed by a synopsis of each of the four pre-meeting conference-call focus areas. Much of the workshop time was spent in whole-group or sub-group discussions to formulate specific, detailed workshop recommendations. Dr. Cyr shared a synopsis of those recommendations with the Council and provided them with a copy the complete workshop summary. The workshop summary including the invited participant list, agenda, and detailed recommendations can be found on the NIDCD website at:

http://www.nidcd.nih.gov/funding/programs/Pages/synaptopathy-summary.aspx

X. Developing the NIH-wide Strategic PlanDr. Lawrence Tabak

Dr. Battey introduced Dr. Tabak, the Principal Deputy Director of NIH who discussed developing the NIH-wide Strategic Plan. In order to advance its mission and fulfill a request from Congress, NIH is developing a 5-year NIH-wide Strategic Plan to outline a vision for biomedical research that will pursue fundamental knowledge about the nature and behavior of living systems and apply that knowledge to extend healthy life and reduce illness and disability. NIH senior leadership and staff from all 27 Institutes, Centers, and Offices (ICOs), with input from the Advisory Committee to the Director of NIH, have developed a framework for the Strategic Plan.



The framework outlined above identifies areas of opportunity that apply across biomedicine and unifying principles to guide NIH in supporting the biomedical research enterprise. The aim is to exemplify the breadth of ICO priorities by identifying major cross-cutting themes. The myriad of important research opportunities for specific disease applications are covered in individual strategic plans from each ICO, and thus will not be the focus of this larger NIH-wide Strategic Plan. The NIH-wide Strategic Plan is due to the Congress in December 2015.

Dr. Tabak responded to questions and solicited comments from the members.

XI. Adjournment

The meeting was adjourned at 1:45 p.m. on September 11, 2015.

XII. Certification of Minutes

We certify that, to the best of our knowledge, the foregoing minutes and attachments are accurate and correct.

Craig A. Jordan, Ph.D. Executive Secretary National Deafness and Other Communication Disorders Advisory Council

October 2, 2015

James F. Battey, Jr., M.D., Ph.D. Chairman National Deafness and Other Communication Disorders Advisory Council

Director
National Institute on Deafness and
Other Communication Disorders

Ginger Webb Council Assistant NDCD Advisory Council

² These minutes will be approved formally by the Council at the next meeting on January 22, 2016, and corrections or notations will be stated in the minutes of that meeting.

APPENDICES

APPENDIX 1	NDCD Advisory Council Roster	12
APPENDIX 2	NIDCD Director's Report Slides	14

Appendix 1

National Deafness and Other Communication Disorders Advisory Council

(Terms end on 5/31 of the designated year)

Chairperson

James F. Battey, Jr. M.D., Ph.D., Director
National Institute on Deafness and Other Communication Disorders
Bethesda, MD 20892

BLACKSTONE, Sarah W., Ph.D. President and CEO Augmentative Communication, Inc. Monterey, CA 93940	2019	MYERS, David G., Ph. D. Professor Hope College Department of Psychology Holland, MI 49422	2017
BLESS, Diane M., Ph.D. Professor Emeritus Departments of Communicative Disorders And Surgery University of Wisconsin – Madison School of Medicine Madison, WI 53792	2018	PERKELL, Joseph S., Ph.D., D.M.D. Research Affiliate Research Laboratory of Electronics Massachusetts Institute of Technology Cambridge, MA 02446	2016
KAYE, Joan Executive Director Sophie's Soundcheck New York, NY 10128	2016	ROBINSON, Jr., Tommie L., Ph.D. Chief, Division of Hearing and Speech Children's Hearing and Speech Center Children's National Medical Center Washington, DC 20009	2016
KINNAMON, Sue C., Ph.D. Professor Department of Otolaryngology University of Colorado, Denver Aurora, CO 80045	2019	SERRANO, Elba E., Ph.D. Regents Professor Department of Biology New Mexico State University Las Cruces, NM 88003	2017
LEE, David J., Ph.D. Professor Department of Public Health Sciences University of Miami School of Medicine Miami, FL 33136	2018	SHANNON, Robert V., Ph.D. Professor of Research Otolaryngology, Biomedical Engineering, and Neuroscience Keck School of Medicine	2015
LI, Jian-Dong, M.D., Ph.D. Georgia Research Alliance Eminent Scholar	2018	University of Southern California Los Angeles, CA 90007	
Director, Center for Inflammation, Immunity and Infection Professor, Department of Biology Georgia State University Atlanta, GA 30303		SMITH, Richard J. H., M.D. Professor Department of Otolaryngology University of Iowa – Carver College of Med Iowa City, IA 52242	2018 icine
LIBERMAN, M. Charles, Ph.D. Director, Eaton-Peabody Laboratory Department of Otology and Laryngology Harvard Medical School Boston, MA 02114	2019	TAGER-FLUSBERG, Helen, Ph.D. Professor Department of Psychological and Brain Sciences Boston University Boston, MA 02215	2016

TUCCI, Debara L., M.D.
Professor
Division of Otolaryngology
Department of Surgery
Duke University Medical Center
Durham, NC 27710

WESTERFIELD, Monte, Ph.D. 2017
Professor and Chair
Institute of Neuroscience
Department of Biology
University of Oregon
Eugene, OR 97403

WILSON, Donald A., Ph. D. 2019
Senior Research Scientist and Deputy Director
Emotional Brain Institute
The Nathan S. Kline Institute for Psychiatric
Research
Professor
New York University School of Medicine
Orangeburg, NY 10962

Ex Officio

2017

BECK, Lucille B., Ph.D. Director Audiology and Speech Pathology Service Department of Veterans Affairs Washington, DC 20422

DAVIS, Rickie, Ph.D.
Team Leader
Hearing Loss Prevention Team
Division of Applied Research and Technology
National Institute for Occupational Safety
And Health (NIOSH)
Cincinnati, OH 45226

Executive Secretary

JORDAN, Craig A., Ph.D.
Director, Division of Extramural Activities
National Institute on Deafness and Other
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Bethesda, MD 20892

BURWELL, Sylvia M. Secretary Department of Health and Human Services Washington, DC 20201

COLLINS, Francis S., Ph.D., M.D. Director National Institutes of Health Bethesda, MD 20892

NIDCD Director's Budget

James F. Battey, Jr., M.D., Ph.D. NIDCD Advisory Council Meeting September 11, 2015

National Institute on Deafness and Other Communication Disorders

September 2015 Council

FY 2016 Budget Levels

FY 2015:

Operating Level \$405,207,000

FY 2016:

President's Budget Request \$416,241,000 House Appropriations Bill \$412,366,000 * Senate Appropriations Bill \$424,860,000 *

^{*}As reported-out by the Full Appropriations Committee.